October 2002

Massachusetts Board of Registration in Pharmacy

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www.state.ma.us/reg/boards/ph/default.htm

Published to promote voluntary compliance of pharmacy and drug law.

Important Announcements

1. Recently passed legislation contained in outside sections of the governor's budget contained several important pharmacy-related provisions.
   a. The structure of the Massachusetts Board of Registration in Pharmacy will be expanded from seven to eleven members. This change calls for the addition of another public member, a long-term care pharmacist, a registered nurse, and physician, together with a caveat that prevents more than two pharmacists from any one practice setting from serving at one time (at the time of appointment). This change goes into effect immediately (as soon as qualified candidates can be appointed by the governor).
   b. Currently, the Board of Registration in Pharmacy is one of 36 boards under the umbrella agency of the Executive Office of Consumer Affairs. Effective January 1, 2003, the Board will be under the jurisdiction of the Department of Public Health (DPH). This may expand the Board's authority, which was previously limited to retail/wholesale pharmacies, to include hospitals and clinics. In addition, pharmacy, nursing, and medicine, as well as five smaller health boards, will be affected by this move.
2. Massachusetts List of Interchangeable Drug Products (105 CMR 720.000) has been amended removing levothyroxine sodium from the Additional List of Interchangeable Drug Products (MLID). This regulation is authorized by M.G.L.c.17,§ 13; M.G.L. c.112 § 12D. This means that pharmacists may no longer interchange prescriptions written for Synthroid and other brands with a BX rating such as Unithroid and Levoxil. In Massachusetts, this would also include A-rated generic substitutions for levothyroxine sodium as well. For example: If a pharmacist substituted Levoxyl for Synthroid, the Board recommends that the pharmacist contact the prescribing practitioner for a new prescription in order to continue therapy. Please keep this in mind when refilling a prescription that has been interchanged in the past and follow accepted standards of practice to ensure proper drug therapy for your patient. The Board suggests you review the Department of Public Health Policy on Midstream Substitution. The most important point is to keep the patient and prescribing practitioner involved in the process. Please consult the following links.
   - DPH Policy: www.state.ma.us/dph/dcp/dfc9734.htm
   - FDA Site: www.fda.gov/cder/ob/docs/queryai.htm
3. Pharmacist renewals will be mailed during the month of October. Please note the increase in renewal fee and the reminder about Continuing Education verification. **Do not sign your renewal until you have conducted a verification of your continuing education credits and are 100% confident of full compliance with regulations. You may be subjecting yourself to perjury and possible disciplinary action if audited.** See: http://www.state.ma.us/reg/boards/ph/cmr/24704.htm#03.
4. The Board will begin making unannounced and announced quality assurance surveys again in the near future. During the visit, the Continuing Quality Improvement Surveyor will be observing professional standards of practice and systems to reduce quality-related events. This is not an enforcement inspection, so please try to assist the surveyor to help your systems "continually improve" and develop reasonable schedules for implementation of Board Best Practices. Your cooperation and follow-up will be very much appreciated.
5. Remember Pharmacy Technician Registration deadline is December 31, 2002. For further information please call PCS toll free 1-877/887-9727.

Recent Board Policies

For a complete list of all Board policies visit our Web site at: www.state.ma.us/reg/boards/ph/pol00000.htm.

Policy Number PH - 2002-01

Policy on Return for Redispensing of Medications from Long-term Care Facilities

In accordance with the authority granted by M.G.L. c. 111, s. 25I, the Department of Public Health (DPH) has adopted a **Policy on Return for Redispensing of Medications from Long-term Care Facilities** permitting long-term care facilities (LTCFs) licensed by the DPH to return certain unused unit-dose packaged and certain other unused Schedule VI and over-the-counter medications to pharmacies for the purpose of redispensing to patients. This DPH policy permits LTCFs to utilize unit-dose packaging for the management and administration of pharmaceuticals to patients.

In accordance with 247 CMR 9.01(4), the Board has voted to adopt the DPH's **Policy on Return for Redispensing of Medications from Long-term Care Facilities** (see www.state.ma.us/reg/boards/ph/misc/att_dph.pdf) and permit the redispensing of certain medications from LTCFs in accordance with DPH policy requirements; **provided that the pharmacist redispensing any previously dispensed prescription or non-prescription drug product has determined, using proper professional judgment, that the drug meets United States Pharmacopeia standards compendia for dispensing.** Additionally, to redispense permitted medications, the pharmacy will be required to have a **written policy** regarding the return for redispensing of Schedule VI and over-the-counter medications returned from LTCFs. The written policy must address patient safety issues including, but not limited to:

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1. Ensuring that the drugs returned were originally dispensed by the same pharmacy;
2. Ensuring that a pharmacist is in control of the redispensing process and has verified each order before redispensing;
3. Ensuring dispensers, repackagers, and ultimate users can be identified and notified in the event of a recall;
4. Minimizing opportunities for tampering and diversion;
5. Verifying the drugs are not expired and have a minimum of three (3) months/ninety (90) days remaining to the beyond use date or expiration date, whichever is earlier;
6. Requiring that the pharmacist obtain assurances from a responsible person in charge of the drugs that the drugs have been stored in accordance with the manufacturer's recommendations and current United States Pharmacopeia standards compendia;
7. **Disallowing** the return or redispensing of any temperature-sensitive drug or any drug requiring refrigeration;
8. **Disallowing** the return or redispensing of any compounded or reconstituted medication;
9. **Disallowing** the return or redispensing of any medication which appears to be adulterated or misbranded;
10. **Disallowing** the return or reuse of any drug designated as Schedule II-V controlled substances, in accordance with M.G.L. c. 94C, s. 3;
11. **Disallowing** the return or reuse of drugs which may have had their integrity, packaging, or labeling compromised (eg, through environmental damage such as water damage, crushing, a broken seal, a torn, or marked label);
12. Requiring the maintenance of a repackaging record, including the name, strength, lot number, quantity, manufacturer and/or distributor information, date of repackaging, number of packages prepared, number of dosage units in each package, signature of person performing the repackaging, signature of the supervising pharmacist, and such other identifying marks as may be added by the pharmacy for recordkeeping purposes;
13. Requiring the maintenance of a packing manifest for each prescription drug returned by the facility to the pharmacy, to be readily retrievable and maintained at the dispensing pharmacy for a minimum of seven years; and
14. Requiring that a pharmacist has determined, using proper professional judgment, that all such drugs are appropriate for redispensing.

Board Develops Best Practices

Best Practice Recommendations to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts

In 2000, in response to medication error rates and distribution issues, the Board convened an advisory committee to make recommendations to the Board regarding continuing quality improvement (CQI) initiatives that could be implemented in all pharmacy practice settings to promote optimum pharmaceutical care. Participants in the Board's CQI Advisory Committee included Board members, representatives from institutional and retail pharmacy settings, professional associations, colleges of pharmacy, the Massachusetts Coalition for the Prevention of Medical Errors, the Department of Public Health, and related regulatory agencies.

The CQI Advisory Committee developed a set of **Best Practice Recommendations** (Recommendations) that could be implemented by the various pharmacy settings according to the particular needs, available resources, and community served by the pharmacy. The Recommendations developed by the CQI Advisory Committee were based on a review of current literature on medication dispensing systems and recent research on the incidence and causes of medication errors, as presented by the Board's Quality Assurance Surveyor and CQI Advisory Committee Chairman (a member of the Board). The CQI Advisory Committee provided comment and direction regarding the Recommendations and forwarded the proposed Recommendations to the Board for adoption.

The Recommendations cover most pharmacy settings and include a variety of measures that can be implemented immediately and other processes that involve technological and training topics that can be instituted over a longer period of time to improve medication delivery systems. This list is **not** exclusive of other improvements that may be necessary to a particular pharmacy setting, and may be supplemented by the Board from time to time.

The Board urges all pharmacies to order the review of these recommendations a high priority and to consider implementation of those measures that are appropriate to the particular pharmacy setting. The Board believes that adoption and institution of these practices will result in improved performance, increased patient safety, a reduction in medication errors, and enhanced pharmacy medication delivery systems in general.

Best Practices to Promote Optimum Pharmaceutical Care in the Commonwealth of Massachusetts

1. **Develop policies and procedures providing that incident reports will be completed and submitted to a national database, such as the United States Pharmacopeia Medication Errors Reporting Program (MERP), for each quality-related event (QRE) occurrence. A QRE is defined as any departure from the appropriate dispensing of a prescribed medication that is not corrected prior to the delivery of the medication.**

   The term "quality-related event" includes variations from the specifications of a prescription, such as wrong drug, wrong strength, wrong directions, and wrong dosage form. The term also includes packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, and the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.

   Recommended Actions
   - Create a system for reporting medication errors to a national database to promote analysis of the occurrence of the Quality Review Event (QRE) and prevent similar events from recurring.
   - Promote a non-punitive atmosphere for reporting of medication errors.
   - Voluntarily report QRE to the USP Medication Error Reporting Program.
2. **Institute a system to review incident reports quarterly generated at the pharmacy. Perform root cause analysis and include information from such review in quality improvement programs. Reviewers should include pharmacists, pharmacy technicians, and appropriate management personnel.**

   Recommended Actions
   - Evaluate the QREs that occurred in the pharmacy on a quarterly basis and identify the root cause of the QREs.
   - Implement improvements/interventions based on the information gathered as part of the root cause analysis.
   - Publicize changes to pharmacy staff.
3. **Develop and implement an effective workflow plan that is evaluated periodically to maximize effective use of space, equipment, and staff.**

   Recommended Actions
   - Develop policies and procedures to ensure that the appropriate individuals are completing appropriate tasks.
   - Consider the use of automated devices to aid staff.
   - Explore ways to optimize patient care services, ie, providing separate area for confidentiality when counseling patients.
   - Evaluate the size of the pharmacy to determine optimum dispensing area.
4. **Routinely poll customers regarding quality of care and satisfaction with service.**

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Recommended Actions

- Develop a customer-focused survey to identify areas of improvement.
- Review the findings of the survey with pharmacy staff to develop solutions to improve patient satisfaction.

5. **Develop and implement a comprehensive technician-training program that requires pharmacy technician trainees to demonstrate competence in functioning as pharmacy technicians and to qualify for registration as pharmacy technicians.**

   Recommended Actions

   - Develop a comprehensive pharmacy technician-training program and provide a copy of the technician-training program to the Board's Technician Training committee for Board approval.
   - Encourage pharmacy technicians registered by the Board to meet and maintain certification requirements.
   - Provide continuing education opportunities for pharmacy technicians.

6. **Implement a policy requiring that counseling be offered to every patient receiving a prescription, regardless of whether the prescription is new or a refill. During patient counseling, the pharmacist should verify that the patient understands the purpose, proper use, and expected outcomes of their drug therapy. Counseling should also include information as to the safe and accurate use of prescribed medications. Educating patients about the safe and effective use of medications promotes patient involvement in their own care and is an important component of any medication error-reduction strategy. Patient counseling may have a beneficial impact by reducing the incidence of quality-related events.**

   Recommended Actions

   - Dispense or recommend proper measuring device (eg, oral dosing spoon) with all liquid medications. Instruct patients or caregivers on how to use the measuring device.
   - Provide written patient drug information materials with all new outpatient prescriptions dispensed.
   - Develop standard counseling procedures that include checks for the following:
     - Right patient
     - Right drug
     - Right drug for this patient
     - Appropriate dosing schedule
     - Appropriate route of administration
     - Correct route of administration for this patient
     - Verification that the patient understands why they are taking the drug
     - Verification that the patient understands how to use the drug

7. **Develop policies and procedures that ensure patient profiles are periodically updated for drug allergies, patient weight, adverse reactions, over-the-counter (OTC) medication usage, and alternative medication/herbal remedy usage.**

   Recommended Actions

   - Develop a policy that requires that allergy information be updated when filling or refilling a prescription.
   - Require that all new prescriptions include allergy information.
   - Develop a policy of updating the patient's weight periodically.
   - Ask patients about their use of OTC medications and herbal remedies and document responses in the patient profile.
   - Update patient profiles periodically. Updates should include information on newly-developed allergies even if the patient is not filling a new prescription.

8. **Utilize available age- and weight-adjusted dosing guidelines when appropriate.**

   Recommended Actions

   - Verify pediatric dosing to ensure proper dose.
   - Develop pediatric- and geriatric-specific guidelines for age- and weight-adjusted dosing.
   - Consider acquiring or utilizing reference materials, textbooks, and/or computer software that directly address pediatric and geriatric dosing.
   - When appropriate and necessary, verify that doses are appropriate for the patient.

9. **Provide adequate and easy access to appropriate reference materials.**

   Recommended Actions

   - Provide Internet access to pharmacists to research clinical information.
   - Establish a clinical department to serve as a resource for dispensing pharmacists.
   - In addition to required reference texts, provide additional reference materials, such as computer software programs, relevant to particular practice setting.

10. **When necessary and appropriate, question adherence to prescriber directions when a medication intended for chronic use is filled more than three days late or when the medication is reordered substantially earlier than expected.**

    Recommended Actions

    - Monitor prescription drug usage among chronic disease state patients to ensure compliance.
    - Ask the patient if a drug therapy change has occurred and, if needed, contact the prescriber to obtain updated information.
    - Ask patients how they feel, paying attention to improvements in the patient's condition as well as adverse effects.

11. **Develop written policies and procedures to assure that outdated stock or stock with an expiration date that does not allow sufficient time for dispensing by the pharmacy or use by the patient is segregated from other stock and either prepared for return to the manufacturer or destroyed and documented.**

    Recommended Actions

    - Periodically inspect the expiration date on the medication stock bottles.
    - Periodically inspect the expiration date on the medication containers in the refrigerator or freezer.
    - Identify short-dated items with a colored label indicating expiration date.
    - Check expiration dates on all products prior to completing the filling and dispensing of medication.

12. **Adopt written policies and procedures pertaining to the handling of filled prescription orders waiting for pick-up by a patient or patient representative.**

    Recommended Actions

    - Verify the patient's name, address, and date of birth when prescription orders are picked up.

13. **Adopt written policies and procedures relating to the return of unclaimed prescriptions to stock.**

    Recommended Actions

    - Adopt a policy that states that only a pharmacist may return medication to the stock with appropriate checks.

14. **Develop procedures to ensure drug recalls are acted upon in a timely manner.**

    Recommended Actions

    - Adopt procedure that personnel receiving recall notice are required to immediately bring the recall notification to the pharmacist's attention.

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15. **Explore the reasons for out-of-stock items.**

Recommended Actions

- Collect data and analyze trends related to out-of-stock items.
- Utilize a computer program to determine inventory employing maximum/minimum strategy.
- Consider auto-replenishment technology.
- Refer to the Food and Drug Administration shortage list.

16. **Adopt a policy allowing pharmacists up to a 30-minute lunch break when they work six or more hours in a day.**

Recommended Actions

- Develop policies and procedures regarding the operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods, in accordance with policies of the Board.
- Develop policies and procedures detailing the authorized duties of ancillary staff during temporary absences of the pharmacist; the pharmacist's responsibilities for checking all work performed by ancillary staff; and the pharmacist's responsibility for maintaining the security of the pharmacy.

17. **Develop policies and procedures regarding proper staffing.**

Recommended Actions

- Periodically review staffing requirements to ensure adequate availability of professional, technical, and clerical staff.
- Ensure that competent staff is available during periods of high activity.

18. **Utilize interpreters as necessary.**

Recommended Actions

- Employ individuals who can speak a second language.
- Learn a second language.
- Engage an interpreter service (such as AT&T).

19. **Develop policies and procedures that continually improve pharmacy practice by incorporating strategies to optimize therapeutic outcomes.**

Recommended Actions

- Consider disease state management programs and certification programs to enhance delivery of pharmaceutical care.
- Initiate a program to monitor HbA1C levels of diabetic patients.
- Counsel patients with diabetes regarding the proper use of glucose-monitoring equipment, insulin, syringes, injection techniques, and insulin pens.
- Implement a program to encourage high-risk patients to have cholesterol levels evaluated.
- Encourage patients with asthma to demonstrate proper use of Metered Dose Inhalers (MDIs), spacers, and peak-flow meters.
- Institute and promote procedures to determine if patients utilizing chronic care medications are adhering to prescribed medical regimens.
- Develop a plan for the acquisition of adherence software within an acceptable time frame.
- Provide counseling and conduct activities to help increase immunization rates for patients at high risk for pneumonia and influenza.

20. **Develop policies and procedures that continually ensures the integrity of Biologicals and Pharmaceuticals.**

Recommended Action

- Consider maintaining a daily temperature log on file to ensure proper storage of biologicals and refrigerated pharmaceuticals.

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Newsletter Funding

The Board gratefully acknowledges that this *Newsletter* is funded through an unrestricted education grant provided by Abbott Laboratories. Chuck Young, State News Editor.

The *Massachusetts Board of Registration in Pharmacy News* is published by the Massachusetts Board of Registration in Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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